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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,884	05/31/2001	Thomas Hoeg-Jensen	6213.200-US	1019

23650 7590 03/05/2007

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PATENT DEPARTMENT
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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/870,884	HOEG-JENSEN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-16,21-26,28 and 29* is/are rejected.

7)☒ Claim(s) *17-20 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-16, 21-26, 28, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-11, 14-28, and 31-35 of copending Application No. 10/307,678. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '678 application anticipate the instant claims. The phenyl group present in the aryl boronate groups of the claimed insulin derivatives of the '678 application corresponds to Applicants' lipophilic substituent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, 5, 6, 11, 16, 21-24, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyazaki et al (U.S. Patent No. 5,478,575). Miyazaki et al teach sugar-responsive polymer complexes which are used to treat diabetes. The polymers are comprised of optionally nitrated benzeneboronic acid groups and are bound to the hydroxy groups of glucosyl-containing insulin derivatives via a boronate ester bond. The polymers have a molecular weight from 5,000 to 300,000 and are easily soluble in alkali solution. Insulin release from the complex is increases or decreases with glucose concentration. See, e.g., the Abstract; column 6, lines 6-13, 30-37, and 43-61; Examples 1, 2, and 5-8; Reference Example 1; and claim 1. The phenyl ring present in the benzeneboronic acid groups corresponds to Applicants' claimed lipophilic substituents. With respect to instant claim 1, in view of the similarity in structure between the insulin derivatives and complexes of Miyazaki et al and Applicants' claimed insulin derivatives, the insulin derivatives of Miyazaki et al are deemed inherently to be soluble aggregate or aggregate-forming to the same extent claimed by Applicants. With respect to instant claim 3, in view of the similarity in structure between the complexes of Miyazaki et al and Applicants' claimed insulin derivatives, the complexes of Miyazaki et al are deemed inherently to have a glucose affinity in the range of 0.01 μM to 10 mM to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the insulin derivatives and complexes of Miyazaki et al and Applicants' claimed insulin derivatives to shift the burden to Applicants to provide evidence that the claimed insulin derivatives are unobviously different than the insulin derivatives and complexes of Miyazaki et al. With respect to instant claim 11, the glucosyl groups and the succinic acid group present in the insulin derivatives of Miyazaki et al correspond to Applicants' linkers.

4. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Miyazaki et al (U.S. Patent No. 5,478,575) as applied against claims 1-3, 5, 6, 11, 16, 21-24, 26, and 28 above, and further in view of the WO Patent Application 84/01896. Miyazaki et al teach that their glucosyl-containing insulin derivatives are formed according to "the national publication of the translated version No. 59-502065 (1984) of Patent Cooperation Treaty" (see, e.g., column 5, lines 64-66, and column 7, lines 41-43). This reference is the WO Patent Application '896 cited above, and teaches that the glucosyl groups are attached to insulin via the GlyA1, PheB1 and/or the LysB29 residues. See, e.g., page 8, lines 19-29, and page 9, lines 13-16. Accordingly, the benzeneboronic acid groups present in the complexes of Miyazaki et al are attached to the insulin through the amino groups of GlyA1, PheB1 and/or the LysB29 residues of the insulin.

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being obvious over Miyazaki et al (U.S. Patent No. 5,478,575) as applied against claims 1-3, 5, 6, 11, 16, 21-24, 26, and 28 above, and further in view of the WO Patent Application 99/21888. Miyazaki et al do not teach combining its glycosylated insulin with an insulin of rapid onset of action. The WO Patent Application '888 shows that it is known to combine aggregating insulin analogues (which have protracted profiles of action) with rapid acting insulin analogues so that the preparation provides both a rapid onset of action as well as a prolonged action profile (see, e.g., page 7, lines 18-22). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine a known rapid acting insulin analogue with the complexes of Miyazaki et al so as to provide a preparation having both a rapid onset of action as well as a prolonged action profile as is taught desirable by the WO Patent Application '888.

6. Applicant's arguments filed January 30, 2007 have been fully considered but they are not persuasive.

It should be noted that Applicants' amendment did not incorporate the limitation of claim 17 into independent claim 1. Note that claim 17 is dependent upon claim 16, which specifies a specific relationship between the glucose-sensing group and the substituent capable of effecting the formation of high molecular aggregates/lipophilic group. The specific relationship required by claim 16 is not present in amended claim 1.

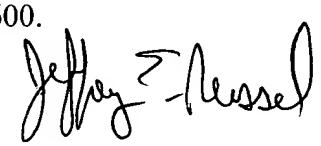
7. Claims 17-20 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 28, 2007